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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/315,688	05/20/99	SHANBROM	E 38786.00069

IM52/1220  
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EXAMINER

OLSEN, K

ART UNIT

PAPER NUMBER

1744

DATE MAILED:

12/20/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.

09/315,688

Applicant(s)

Shanbrom

Examiner

Kaj Olsen

Group Art Unit

1744



☒ Responsive to communication(s) filed on Oct 3, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-5 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-5 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 101*

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-5 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

In applicant's response to the previous 101 rejection, applicant has respectfully traversed the rejection on a number of grounds. Applicant first argues that an antioxidant by definition is a reducing substance (page 2, line 17 of response), or more specifically, a substance which is oxidizable by iodine (page 3, line 16 of response). However, it is not clear how applicant arrived at this definition of antioxidant. Both the Kirk-Othmer Encyclopedia and the Glossary of Chemical Terms define an antioxidant as being a substance capable of retarding oxidation. Neither of these definitions appear to equate the materials reducing power with its antioxidant qualities. It is possible that most (if not all) antioxidants are, in fact, reducible substances. However, both references above appear to indicate the material must also be capable of inhibiting auto-oxidation presumably by some free radical mechanism (see Kirk-Othmer, reactions 11-17). The mere fact that a material is reducible does not mean it is also an antioxidant if it is not capable of inhibiting the oxidation by free radical termination. Applicant points out that

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materials mentioned by Alexander, such as cysteine, are considered antioxidants. That may be the case, but Alexander lists other materials which the examiner does not believe have any known antioxidant qualities. In addition, even if the only criteria for being an antioxidant were to be a reducible substance, it is unclear the significance of being reducible by iodine. Almost any known material is reducible it is exposed to another material which is more oxidizable than the first material is reducible. Why is iodine being utilized as the criteria for an antioxidant? Clarification as to how the definition offered by the applicant in the response corresponds to the art recognized definition of antioxidants is requested.

The applicant is correct in pointing out that a number of materials listed by Alexander do not undergo known oxidation, but rather iodination where iodide ion would not appear. However, this only indicates the reaction of iodine with these materials is more favorable for the formation of the iodinated substances than the formation of iodide ions. An innumerable number of material which are reducible by iodine and results in the formation of iodide ions exist. This is possibly suggested by applicant's table 1 where the baseline IRU reading before the ingestion of the antioxidant material showed a baseline value of almost 800. Unless the test subject ingested large amounts of antioxidants prior to the test, the PVP-I must be reacting with something else in the subject's urine.

Applicant also traverse the examiner's query concerning the absence of calibrations. To clarify, the examiner's concern is not about calibration per se, but the absence of any indication this technique is useful for antioxidants as a whole. The examiner knows of no unifying aspect

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of antioxidants that would suggest that because any one known antioxidant (e.g. ascorbic acid, or SHANSTAR) reacts with iodine to produce iodide ions, that other known (or even unknown) antioxidants would produce like responses. Antioxidants appear to be materials which inhibit the formation of hydroperoxides by the materials own ability to form free radicals (again, Kirk-Othmer, reactions 11-17). How this property of antioxidants as a whole can be discerned by the reaction of iodine with all antioxidants is entirely unclear.

3. Claims 1-5 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 5 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chen (Chemical Sensors, vol. 15, pp. 295-297 (1995)).

For the purpose of applying prior art, the examiner is treating the claims here solely based on the particular steps of the claims and is obviating the issues raised above in the rejection under 35 USC 101, and 112 1st paragraph.

Based on the CAS abstract, Chen discloses a method of determining the level of ascorbic acid, which is a known antioxidant, by exposing said sample to elemental iodine and measuring a change in concentration of iodide ions using a iodide-cyanide selective electrode. Although the abstract does not mention the electrode being iodide-selective, an oral translation of the abstract confirmed the disclosed electrode is both a iodide and cyanide selective electrode (presumably

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because there are similarly sized mono-anions). Although the examiner is unclear whether Chen teaches the utilization of an iodine solution (as opposed to solid iodine), it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize an iodine solution as the reagent source of iodine because a solution is easier to handle and easier for transporting known aliquots of reagent. Also solid iodine is caustic and is prone to sublimation.

7. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of Coetzee (S. Afr. Tydskr, Chem., vol. 44, pp. 22-24 (1991)).

Chen disclosed all the limitations of the claim, but did not disclose the use of a solution of iodine with an iodophor. However, Coetzee in an alternate analytical technique disclosed that iodine complexed with iodophors such as polyvinylpyrrolidone is a preferable source of iodine due to its greater stability than that of iodine solutions (see first paragraph). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize an iodophor in order to stabilize the source of iodine.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Karlsson.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506.

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If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for this Group is (703) 305-7719.

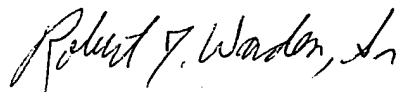
Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

Kaj K. Olsen, Ph.D.



Patent Examiner

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